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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,904	07/10/2003	Laura T. Bortolin	0050.2060-001	1657

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EXAMINER	
BERTAGNA, ANGELA MARIE	
ART UNIT	**PAPER NUMBER**
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,904	BORTOLIN ET AL.	
	Examiner	Art Unit	
	Angela Bertagna	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *10-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

Status of the Application

Applicant's response filed October 2, 2006 is acknowledged. Claims 1-24 are currently pending. Claims 1 and 2 have been amended. Claims 10-21 are withdrawn from consideration as being drawn to a non-elected invention. Claims 22-24 are new.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Pourahmadi et al. (US Patent No. 6,440,725 B1).

Pourahmadi discloses a nucleic acid purification cartridge (abstract and Figure 2).

With regard to claims 1 and 9, Pourahmadi teaches an apparatus comprising:

(a) a porous support including a deactivating agent that deactivates a nucleic acid amplification inhibitor (column 6, lines 1-4; note that the filter may be designed to trap amplification inhibitors: column 12, lines 33-50, especially lines 33-40 which teach that reagents may be embedded in the membrane filter)

(b) a housing having an opening and defining an interior, where the interior is in fluid communication with the porous support (column 3, line 65 – column 4, line 7; where the "external instrument for receiving the cartridge" is the equivalent of the instantly claimed housing. Note that the instrument is in fluid communication with the cartridge that contains a porous support – see Figure 2),

whereby at least a portion of a fluid directed through the opening is directed through at least a portion of the porous support and separates at least a portion of a nucleic acid component of the sample contacting the porous support from the support (see Figure 2, where lysing chamber 119 contains a filter to remove PCR contaminants; see also column 6, lines 1-4 and column 12, lines 33-50, cited above),

and whereby deactivated components of the nucleic acid amplification inhibitor component are retained by the porous support or are soluble fragments that do not interfere with nucleic acid amplification procedures, thereby preparing the nucleic acid component for amplification (see column 12, lines 33-50, where lines 45-50 teach trapping of PCR inhibitors/contaminants on filters embedded with deactivating reagents; see also column 32, lines 51-64 which teaches that the nucleic acids are bound to the filter, whereas deactivated inhibitors are removed from the filter in a wash and funneled to a waste chamber (i.e. the inhibitors become soluble fragments that do not interfere with nucleic acid amplification procedures)

(c) a magnetic substrate that separates the sample to be contacted with the porous support from at least a portion of a raw sample and deposits the sample at the porous support (column 18, lines 40-50 where functionalized magnetic beads are taught as a

means of moving the nucleic acids between regions of the cartridge; column 12, lines 30-31 teach streptavidin coating).

With regard to claim 2, the magnetic substrate taught by Pourahmadi is included in a separating means that comprises:

(a) a vessel having an inlet at a first end and an outlet at a second end, distal to said first end (column 18, lines 40-50 teach a reservoir of magnetic beads in the cartridge; column 6, lines 8-17 teach that the capture area **122** of the cartridge is a microfluidic structure with an inlet and outlet; see also Figure 2)

b) an ampoule contained within the vessel, said ampoule containing magnetic beads (column 18, lines 40-50)

c) a valve at the second end of the vessel (see Figure 2 and column 6, line 67 – column 7, line 1)

d) a magnet at said valve (column 18, lines 45-52).

With regard to claim 3, Pourahmadi teaches the use of AC electromagnetic fields to cause the magnetic beads contained in a reservoir to "circulate within a small region of the cartridge to mix fluids within the cartridge" (column 18, lines 48-50). Since all fluids inherently have some buffering capacity, this disclosure of Pourahmadi meets the instant limitation that the ampoule contains a buffer solution.

With regard to claims 4-5 and 7, Pourahmadi teaches that the valve is rotatable, whereby magnetic beads held at one end of the valve can be moved to a second end of the valve and thereby placed into contact with the porous support, and further, that the magnet is removable from the valve, whereby the magnetic beads can be attached to the magnet within the vessel

while the valve is in one position, and while the valve is in a second position, the magnet can be removed and the magnetic beads released into contact with the porous support (column 18, lines 40-62). Also, note that since Pourahmadi states that this system allows the user to maintain complete fluid control, this inherently includes movement of the magnetic beads in an upward direction if desired.

With regard to claim 6, the cartridge of Pourahmadi includes a removable cap for sealing off the lysing chamber that is located at the first end of the interconnected vessel (column 32, lines 40-50 and Figure 16).

With regard to claim 8, the "external instrument" that is the equivalent of the claim housing may be detached from the cartridge (see Figure 3).

With regard to claim 22, Pourahmadi teaches that the deactivating agent is a chaotropic agent (column 12, lines 33-50 teach membranes containing reagents to effect cell lysis, release target nucleic acids and separate contaminants; column 12, line 29 teaches that detergents may be dried reagents; column 16, lines 35-39 teaches specific detergents and the use of GuSCN for cell lysis. In addition to the chaotrope GuSCN, detergents are also chaotropic agents, because they have the ability to destabilize hydrogen bonding and hydrophobic interactions).

With regard to claim 23, Pourahmadi teaches that the magnetic substrate is located between the opening and the porous support (column 18, lines 40-50).

With regard to claim 24, Pourahmadi teaches that directing fluid through the porous support also separates at least a portion of a nucleic acid component of the sample from the nucleic acid amplification inhibitor component retained by the porous support (column 12, lines 45-48 teach that the filters can "simultaneously physically entrap target cells, lyse cells, and bind

either target analytes **or** competing contaminants or analytical reaction inhibitors." Therefore, directing fluid through the porous support separates a portion of a nucleic acid component from support-bound amplification inhibitors).

Response to Arguments

Objections to the Specification

Applicant's arguments, see page 10, filed October 2, 2006, with respect to the objection to the abstract have been fully considered and are persuasive. Applicant's corrected abstract does not contain legal language, and therefore, the objection has been withdrawn.

Objections to the Drawings

Applicant's arguments, see page 10, filed October 2, 2006, with respect to the objection to the drawings have been fully considered and are persuasive. Applicant's submission of replacement drawing sheets overcomes the objection, and therefore, it has been withdrawn.

Rejections under 35 U.S.C. 102

Applicant's arguments, see pages 12-13, filed October 2, 2006, with respect to the rejection of claim 1 under 102(a) and 102(e) as anticipated by Dority (US 6,374,684 B1) have been fully considered and are persuasive. Dority does not teach all of the elements of the amended claim 1, and therefore, this rejection has been withdrawn.

Applicant's arguments filed October 2, 2006 with respect to the rejection of claims 1-9 under 102(a) and 102(e) as anticipated by Pourahmadi have been fully considered but they are

not persuasive. Applicant argues that Pourahmadi does not teach the apparatus of the amended claim 1. More specifically, Applicant argues that Pourahmadi does not teach a porous support that includes a deactivating agent or a magnetic substrate that separates a sample from a raw sample and deposits the sample at a porous support (see page 11 of the response). These arguments were carefully considered, but were not found persuasive, because as discussed above, Pourahmadi does teach all of the elements of the amended claims.

Regarding parts (a) and (b) of claim 1, Pourahmadi teaches a porous support, specifically a membrane or filter, that has been embedded with dried reagents for cell lysis (see column 12, lines 33-50). More specifically, Pourahmadi expressly states, "Dried reagents may also be contained within a membrane material that can be employed as an interactive region by physical incorporation of the material into a region in communication with fluidic channels...Such membranes are designed to capture cells, effect lysis of host cells, release target nucleic acids, and separate contaminants that may interfere with the polymerase chain reaction or other analytical events (column 12, lines 33-43)." Pourahmadi further teaches that the membrane filters may bind either target nucleic acids **or** PCR inhibitors (column 12, lines 45-50). Therefore, the filters taught by Pourahmadi include an agent that deactivates and retains PCR inhibitors or releases the inhibitors as soluble fragments to a waste reservoir where they cannot interfere with amplification.

Regarding part (c) of claim 1, Pourahmadi teaches that the cartridge contains a reservoir of functionalized magnetic beads (column 18, lines 42-45). Pourahmadi further teaches that these functionalized magnetic beads "may be vibrated or moved from one region to another (column 18, lines 45-47)." Therefore, when the functionalized magnetic beads are located in the

lysing chamber, they "separate the sample to be contacted with the porous support from at least a portion of a raw sample" and also "deposit the sample at the porous support." Therefore, since Pourahmadi teaches all of the elements of the amended claim 1, the rejection of claims 1-9 and 22-24 under 35 U.S.C. 102(a) and 102(e) as anticipated by Pourahmadi is maintained.

Conclusion

No claims are currently allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Harvey et al. (US 5,939,259; cited on IDS) teaches reagent-coated membranes that that trap PCR inhibitors, but do not specifically bind nucleic acids. Deggerdal et al. (Biotechniques (1997) 22(3): 554-557) teaches purification of nucleic acids using magnetic beads.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Angela Bertagna
Examiner, Art Unit 1637
December 14, 2006

amb

JEFFREY FREDMAN
PRIMARY EXAMINER
12/18/06